In Re the Application of:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit: 1644

Examiner: J. Roark

RESPONSE TO

RESTRICTION REQUIREMENTECH CENTER 1600/2900

Serial No.: 09/513,024 Filed: February 25, 2000

Atty. File No.: 2879-64

VILEN et al.

"PRODUCT AND METHOD FOR

TREATMENT OF CONDITIONS ASSOCIATED WITH RECEPTOR-

DESENSITIZATION"

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231 ON SHERIDAN ROSS P.C.

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

This response is directed to the restriction requirement dated August 31, 2000. This response is believed to be timely and therefore, no fees are enclosed. In the event that fees are due in connection with this response, please debit Deposit Account No. 19-1970.

The Examiner has restricted the present application into five groups of claims, as follows: Group I (Claims 1-33), directed to a method to desensitize a receptor with a regulatory compound; Group II (Claims 34-43), directed to an isolated regulatory compound that desensitizes a receptor; Group III (Claims 44-46), directed to a method for identifying compounds useful for desensitizing a receptor by causing dissociation of the receptor; Group IV (Claims 47 and 48), directed to a method for identifying compounds useful for desensitizing a receptor by inhibiting association of receptor components; and Group V (Claim 49), directed to a method of sensitizing a receptor. Applicants provisionally elect with traverse to prosecute Group I (Claims 1-33).

The Examiner has also required a species election for the Group I claims. Applicants provisionally elect, with traverse, the following species as required by the Examiner:

- (i) wherein the receptor is: a B cell receptor;
- (ii) wherein the receptor desensitization is due to: dissociation of components;
- (iii) wherein the regulatory compound is: antibody;

- (iv) wherein the antibody: is specific for the transducer component;
- (v) wherein the transducer component is: **Ig**α;

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- (vi) wherein the B cell receptor is expressed by: an autoreactive B cell;
- (vii) wherein the autoimmune disease is: SLE;
- (viii) wherein the Ig Fc receptor is: Fc∈RI
- (ix) wherein the cell type is: a mast cell; and,
- (x) wherein the therapeutic composition is administered: in vivo.

With regard to the Examiner's species election requirement, Applicants note that such a requirement is primarily, if not solely, intended to facilitate a search by the Examiner. Applicants note that the Examiner is obligated to examine the generic claims and submits that the scope of the claims of the present invention is not limited to the elected species. Although all species groups are traversed on the basis that the search for the generic claims would be sufficient to examine all claims, Applicants particularly traverse the species election in group (ii) and (v).

With regard to the species of group (ii), Applicants submit that to separate the claims on the basis of whether the method dissociates the receptor components or inhibits the association of the receptor components is not meaningful, because such a division would not be expected to facilitate the Examiner's search. The concept of the invention is the interference with the physical association between the receptor components, and Applicants submit that a search for this concept is sufficient to address the possible mechanisms by which this can be achieved. Such a species election only serves to increase expense to Applicants and the Patent Office.

With regard to the species of group (v), Applicants initially note that the transducer components of $Ig\alpha$ and $Ig\beta$ always occur together (i.e., there is never a scenario in nature where one occurs without the other). Therefore, even though a regulatory compound could bind to one chain or the other, the effect with regard to the claimed method would be expected to be the same. Thus, Applicants submit that for the purposes of search and examination, the separation of the two components into species is not meaningful. Such a species election only serves to increase expense to Applicants and the Patent Office.

Applicants also traverse the restriction between Groups I, III, and IV, on the basis that a search for one group would be sufficient to examine the claims of the other groups. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in

one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. Section 803. Applicants submit that a thorough search for the subject matter of Group I should also include the subject matter of Groups III and IV. In the present case, the subject matter of these Groups cited by the Examiner is sufficiently small and is so closely related as to be capable of examination together. The restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office. Applicants respectfully request that the Examiner withdraw the restriction requirements.

Sec. 15. 3

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement between Groups I, III and IV.

Date: September 28, 2000

Respectfully submitted,

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